NOV 19 2003

ScoutPro
Special 510(k) Premarket Notification

1. 510(k) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ScoutPro
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Percutaneous Catheter
Product Code:	DQY

General Description:

The ScoutPro is designed to assist with introducing leads into the vessels of the left heart via the coronary sinus. It facilitates access to the coronary sinus venous system as well as probing of the coronary sinus. The ScoutPro has been expanded and modified from BIOTRONIK's currently legally marketed SCOUT (K020821, 06-03-02). The following ScoutPro accessories are the subjects of this 510(k):

ScoutPro 8F that contains the following components:

- 1 hemostatic valve
- 2 guiding catheters BIO 1 and BIO 2
- 1 dilator for the guiding catheter
- 1 peel-away sheath 11F
- 1 guide wire
- 1 needle
- 1 syringe
- 2 slitter tools 4.9 F and 6.3 F for different lead sizes

ScoutPro Sheath "Hook" that contains the following components:

- 1 guiding catheter "Hook"
- 1 dilator for the guiding catheter

ScoutPro Sheath "Multi-Purpose Hook" that contains the following components:

- 1 guiding catheter "Multi-Purpose Hook"
- 1 dilator for the guiding catheter

ScoutPro Sheath "Amplatz 6.0" contains the following components:

- 1 guiding catheter "Amplatz 6.0"
- 1 dilator for the guiding catheter

Indication for Use:

The intended use of the ScoutPro is for introducing leads into the vessels of the left heart via the coronary sinus.

Name and Address of Manufacturers:

BIOTRONIK GmbH & Co. KG (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland 011-41-1-864-5169

Contact Person(s) and Phone Number:

Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374 Fax (503) 635-9936

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2003

BIOTRONIK, Inc.
c/o Mr. Jon Brumbaugh
Director, Regulatory Affairs
6024 Jean Road
Lake Oswego, OR 97035

Re: K033320
Trade Name: SCOUTPro
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: October 13, 2003
Received: October 15, 2003

Dear Mr. Brumbaugh:

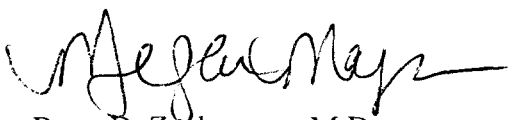
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033320

510(k) Number (if known):

Device Name: SCOUTPro

Indications For Use:

The intended use of the SCOUTPro is for introducing leads into the vessels of the left heart via the coronary sinus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033320

(Optional Format 3-10-98)